In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 20-1905V

LINDA TIMBERLAKE,

Petitioner,

v.

SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent.

Chief Special Master Corcoran

Filed: April 23, 2024

Amy A. Senerth, Muller Brazil, LLP, Dresher, PA, for Petitioner.

Meghan Murphy, U.S. Department of Justice, Washington, DC, for Respondent.

RULING ON ENTITLEMENT[1]

On December 18, 2020, Linda Timberlake filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, *et seq.*[2] (the "Vaccine Act"). Petitioner alleges that she suffered a left shoulder injury related to vaccine administration ("SIRVA"), a defined Table Injury, after receiving an influenza ("flu") vaccine on September 5, 2019. Petition at 1, ¶ 2.

The parties dispute Petitioner's success in establishing the pain onset needed for a Table SIRVA. For the reasons discussed below, I find that the onset of Petitioner's left

[1] Because this Ruling contains a reasoned explanation for the action taken in this case, it must be made publicly accessible and will be posted on the United States Court of Federal Claims' website, and/or at https://www.govinfo.gov/app/collection/uscourts/national/cofc, in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2018) (Federal Management and Promotion of Electronic Government Services). **This means the Ruling will be available to anyone with access to the internet.** In accordance with Vaccine Rule 18(b), Petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

[2] National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all section references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2018).

shoulder pain occurred within 48 hours of vaccination, and she has satisfied the other requirements of a compensable Table SIRVA injury. Petitioner is thus entitled to compensation under the Vaccine Act.

I. Relevant Procedural History

Along with the Petition, Ms. Timberlake filed some of the medical records required under the Vaccine Act. Exhibits 1-5, filed Dec. 18, 2020, ECF No. 1. Over the subsequent five-month period, she filed the remaining medical records and a signed statement.[3] Exhibits 6-7, filed Jan. 27, 2021, ECF No. 8; Exhibit 8, filed May 10, 2021, ECF No. 9. On September 14, 2021, the case was activated and assigned to the "Special Processing Unit" (OSM's adjudicatory system for resolution of cases deemed likely to settle). ECF No. 12.

On October 20, 2022, Respondent stated he was willing to engage in settlement discussions. ECF No. 20. Over the subsequent eight-month period, the parties attempted to reach an informal resolution, but ultimately could not do so, and therefore I set a deadline for Respondent's Rule 4(c) Report. Status Report, filed Aug. 2, 2023, ECF No. 30.

On October 23, 2023, Respondent filed his Rule 4(c) Report, opposing compensation in this case. ECF No. 33. Emphasizing the over two-month delay before Petitioner sought treatment for her left shoulder pain, Respondent insists "the contemporaneous medical records do not demonstrate that there is preponderant evidence of onset of pain within 48 hours of vaccination." *Id.* at 5. Respondent raises no other issue and asks that I "find that this case is not appropriate for compensation under the Vaccine Act." *Id.* at 6.

II. Finding of Fact Regarding Onset

At issue is whether Petitioner's first symptom or manifestation of onset after vaccine administration (specifically pain) occurred within 48 hours as set forth in the Vaccine Injury Table and Qualifications and Aids to Interpretation ("QAI") for a Table SIRVA. 42 C.F.R. § 100.3(a) XIV.B. (influenza vaccination); 42 C.F.R. § 100.3(c)(10)(ii) (required onset for pain listed in the QAI).

[3] Petitioner's statement was not signed under penalty of perjury as required by 28 U.S.C.A. § 1746. Exhibit 8.

A. Authority

Pursuant to Vaccine Act Section 13(a)(1)(A), a petitioner must prove, by a preponderance of the evidence, the matters required in the petition by Vaccine Act Section 11(c)(1). A special master must consider, but is not bound by, any diagnosis, conclusion, judgment, test result, report, or summary concerning the nature, causation, and aggravation of petitioner's injury or illness that is contained in a medical record. Section 13(b)(1). "Medical records, in general, warrant consideration as trustworthy evidence. The records contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium. These records are also generally contemporaneous to the medical events." *Cucuras v. Sec'y of Health & Hum. Servs*., 993 F.2d 1525, 1528 (Fed. Cir. 1993).

Accordingly, where medical records are clear, consistent, and complete, they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Hum. Servs*., No. 03-1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). However, this rule does not always apply. "Written records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent." *Murphy v. Sec'y of Health & Hum. Servs.*, No. 90-882V, 1991 WL 74931, *4 (Fed. Cl. Spec. Mstr. April 25, 1991), quoted with approval in decision denying review, 23 Cl. Ct. 726, 733 (1991), *aff'd per curiam*, 968 F.2d 1226 (Fed.Cir.1992)). And the Federal Circuit recently "reject[ed] as incorrect the presumption that medical records are accurate and complete as to all the patient's physical conditions." *Kirby v. Sec'y of Health & Hum. Servs.*, 997 F.3d 1378, 1383 (Fed. Cir. 2021).

The United States Court of Federal Claims has outlined four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document everything reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist. *La Londe v. Sec'y of Health & Hum. Servs*., 110 Fed. Cl. 184, 203-04 (2013), *aff'd*, 746 F.3d 1335 (Fed. Cir. 2014).

The Court has also said that medical records may be outweighed by testimony that is given later in time that is "consistent, clear, cogent, and compelling." *Camery v. Sec'y of Health & Hum. Servs*., 42 Fed. Cl. 381, 391 (1998) (citing *Blutstein v. Sec'y of Health & Hum. Servs*., No. 90-2808, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998). The credibility of the individual offering such fact testimony must also be determined.

Andreu v. Sec'y of Health & Hum. Servs., 569 F.3d 1367, 1379 (Fed. Cir. 2009); *Bradley v. Sec'y of Health & Hum. Servs*., 991 F.2d 1570, 1575 (Fed. Cir. 1993).

A special master may find that the first symptom or manifestation of onset of an injury occurred "within the time period described in the Vaccine Injury Table even though the occurrence of such symptom or manifestation was not recorded or was incorrectly recorded as having occurred outside such period." Section 13(b)(2). "Such a finding may be made only upon demonstration by a preponderance of the evidence that the onset [of the injury] . . . did in fact occur within the time period described in the Vaccine Injury Table." *Id*.

The special master is obligated to fully consider and compare the medical records, testimony, and all other "relevant and reliable evidence contained in the record." *La Londe*, 110 Fed. Cl. at 204 (citing Section 12(d)(3); Vaccine Rule 8); *see also Burns v. Sec'y of Health & Hum. Servs*., 3 F.3d 415, 417 (Fed. Cir. 1993) (holding that it is within the special master's discretion to determine whether to afford greater weight to medical records or to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such determination is rational).

B. Analysis

I make the onset finding after a complete review of the record to include all medical records, affidavits or declarations, and additional evidence filed. Specifically, I base the findings on the following evidence:

- Prior to vaccination, Petitioner suffered from type 2 diabetes, high blood pressure, high cholesterol, arthritis, and common illnesses. Exhibit 1 at 6; Exhibit 5; Exhibit 7 at 7-52.

- On September 5, 2019, Petitioner received the flu vaccine intramuscularly in her left deltoid at an appointment with her endocrinologist for treatment of her diabetes. Exhibit 1 at 5; Exhibit 6 at 4.

- Approximately two months later (on November 8, 2019), Petitioner visited her primary care provider ("PCP"), complaining of constant pain which worsened with movement since receiving a flu vaccine at her September 5th endocrinology appointment. Exhibit 7 at 53. Upon examination, she exhibited tenderness and pain but normal range of motion ("ROM"). *Id.* at 55. Her PCP diagnosed her with acute left shoulder pain, prescribed

Naproxen,[4] and referred her to occupational/physical therapy ("OT/PT"). *Id.* at 56. He stressed that Petitioner should return if her pain continued. *Id.*

- On November 20, 2019, Petitioner attended her first OT session for "left shoulder and upper arm pain [that] began after getting a flu shot at her doctors [sic] office." Exhibit 2 at 5. Reporting that her pain had not decreased and "[wa]s now interfering with reaching, lifting, and sleeping" (*id.*), Petitioner was assessed as exhibiting decreased strength and ROM and increased pain and edema (*id.* at 7). It was recommended that she attend additional OT sessions. *Id.* at 8.

- The next day, on November 21, 2019, Petitioner visited her PCP for a pap smear. Exhibit 7 at 60. There is no mention of her left shoulder pain in the record from this visit. *Id.* at 60-65.

- Petitioner's condition improved while attending four more OT sessions and performing home exercises during December. Exhibit 2 at 9-41. By December 12, 2019, she demonstrated an increased ROM and less pain. *Id.* at 36. However, additional OT was recommended. *Id.* at 36-37.

- On December 19, 2019, Petitioner returned to her PCP, for treatment of her diabetes and left shoulder pain. Exhibit 7 at 69. Again, it was noted that her left shoulder pain began after her flu vaccine on September 5, 2019. *Id.* at this visit, Petitioner was observed as having pain, tenderness, and decreased ROM and strength. *Id.* at 71. She was prescribed prednisone and referred to an orthopedic surgeon. *Id.* at 72.

- When Petitioner presented to the orthopedist on January 2, 2020, she reported improvement with PT, but also was experiencing continued constant, throbbing, and aching pain that radiated down her upper arm to her elbow. Exhibit 3 at 7. Although Petitioner's inflammation had improved after taking the prescribed prednisone, her discomfort continued. *Id.*

- At this orthopedic visit, Petitioner again described her pain as beginning after her flu vaccine. *Id.* at 7, 10. Although she identified the date of vaccination (September 5, 2019) as the symptom onset date, one entry specifies that her left shoulder pain started the day *after* vaccination. *Compare id.* at 10 *with id.* at 7.

[4] Naproxen is "a nonsteroidal anti-inflammatory drug that is . . . used to treat pain, inflammation, osteoarthritis, rheumatoid arthritis," and other conditions. DORLAND'S ILLUSTRATED MEDICAL DICTIONARY ("DORLAND'S") at 1232 (32th ed. 2012).

- X-rays taken that day revealed a "[w]ell-maintained glenohumeral space with small inferior humeral osteophyte [and] AC arthritis with a superior bone spurs [sic]." *Id.* at 9. And the orthopedist observed some tenderness and mild limitations in ROM, but normal strength. *Id.* at 8.

- Stating that the examination findings were "suggestive of impingement/bursitis," the orthopedist expressed hesitancy to administer a cortisone injection so soon after Petitioner completed her course of steroids. Exhibit 7 at 9. He instructed Petitioner to continue PT and resume taking Naproxen for her pain, adding that he would recommend an ultrasound (to check for a swollen subacromial bursa) or MRI (to check for internal derangement) if Petitioner's symptoms continued. *Id.* He opined that the latter condition was "low" on his list of differential diagnoses. *Id.*

- In January 2020, Petitioner attended four additional OT sessions. Exhibit 2 at 42-69. At the last of these sessions, on January 30, 2020, Petitioner recalled "2 incidents causing increased left shoulder pain over the last week" – when she pulled herself in a van using her left arm and when she moved suddenly when splattered by grease while frying bacon. *Id.* at 63.

- On February 6, 2020, Petitioner returned to her orthopedist, reporting improvement in her ROM but continued left shoulder pain. Exhibit 3 at 13. The orthopedist ordered an MRI. *Id.* at 14.

- Performed on February 16, 2020, the MRI revealed no full-thickness rotator cuff tear, a small interstitial tear of the infraspinatus tendon, mild supraspinatus and long head biceps tendinosis, findings consistent with adhesive capsulitis, moderate to severe acromioclavicular degenerative joint disease with active inflammation, a nondisplaced superior chondrolabral junction tear without paralabral cyst. Exhibit 3 at 42.

- A few days later, on February 19, 2020, Petitioner returned to the orthopedist to discuss the result of the MRI. Exhibit 3 at 17-21. The medical record from this visit contains a detailed history of Petitioner's symptoms and treatment that again included a report that her left shoulder pain started in September 2019, after a flu vaccine. *Id.* at 17. The orthopedist stated, "I think that there is a possibility that the flu injection caused some subacromial bursitis [but] I cannot say that this caused the labrum or rotator cuff partial tears." *Id.* at 17-18. He recommended Petitioner undergo arthroscopic surgery, and she agreed. *Id.* at 18.

- Almost one month later, on March 16, 2020, Petitioner attended a pre-op visit with her PCP, reporting only some heightened anxiety due to the worldwide COVID Pandemic. Exhibit 7 at 74. Petitioner was determined to be medically stable and able to undergo the planned surgery. *Id.* at 77.

- On March 24, 2020, Petitioner underwent arthroscopic surgery which included extensive debridement, subacromial decompression with partial acromioplasty, rotator cuff repair, and excision of the distal clavicle. Exhibit 4 at 6.

- One week after her surgery, Petitioner attended her first post-surgical visit with her orthopedist. Exhibit 3 at 26. She reported that she was doing well, taking Norco[5] for her pain, performing her home exercises, and would attend her first post-surgical PT session the next day. *Id.* at 28.

- At the initial PT evaluation, performed on April 2, 2020, Petitioner reported that her surgery went well; that she was applying ice, performing her home exercises, and wearing her sling during the day and at night; and that her pain was well controlled[6] despite having finished her prescribed Norco that day. Exhibit 2 at 70. This record includes a description of Petitioner's surgery, stating that it was "secondary to shoulder injury following flu vaccine in September 2019." *Id.*

- At her next PT session on April 6, 2020, Petitioner reported pain at a level of three out of ten, adding that she had requested a refill of the prescribed Norco. Exhibit 2 at 79. By her fourth PT session on April 13, 2020, Petitioner reported that she had no pain at rest and had not needed pain medication, either prescribed or over the counter. *Id.* at 92.

- On May 7, 2020, Petitioner had a telephonic appointment with her PCP for follow-up of her rotator cuff surgery, anxiety, and diabetes. Exhibit 7 at 80. She noted that PT was going well, and her ROM was improving. *Id.*

- Petitioner was discharged from PT on July 27, 2020, after 17 sessions. Exhibit 2 at 177. At that time, she was experiencing full strength and only minimal pain and tightness at the extremes of her ROM. *Id.*

[5] Norco is the "trademark for combinations preparations of hydrocodone bitartrate and acetaminophen." DORLAND'S at 1290

[6] Rating her pain as ranging from zero to five, Petitioner reported no pain at this visit. Exhibit 2 at 70.

- Petitioner was seen by her orthopedist one more time on July 30, 2020. Exhibit 3 at 36. She reported that she was doing well, and that her pain was controlled. Noting that Petitioner had been an excellent patient and worked hard in PT sessions, the orthopedist instructed her to continue her home exercises and return on an as needed basis. *Id.*

- On November 17, 2020, Petitioner participated in a telephonic appointment with PCP. Exhibit 7 at 83-87. There is no mention of any left shoulder pain or other issues in the medical record from this visit. *Id.*

- In her declaration signed on April 29, 2021 (but not notarized or signed under penalty of perjury), Petitioner addressed the basic requirements of Section 11(c). Exhibit 8. Regarding her pain onset, she stated that she "noticed the pain right after [she] got vaccinated . . . [and] made an appointment because the pain wouldn't go away." *Id.* at ¶ 3. Petitioner insists she was "in unbearable pain from the time [she] had [her] vaccination until [she] recovered from surgery." *Id.*

The record as a whole supports Petitioner's description of left shoulder pain beginning within 48 hours of vaccination. In multiple post-vaccination medical records, Petitioner consistently reported pain that began upon vaccination. Exhibit 7 at 52; Exhibit 2 at 5; Exhibit 7 at 69; Exhibit 3 at 7, 10; Exhibit 3 at 17 (in chronologic order). When she first visited her orthopedist, she provided detailed information related to the onset of her left shoulder pain, placing onset within 48 hours of vaccination.[7]

Without fail, Petitioner attributed her injury to the flu vaccine she received in September 2019. *Id*. And her orthopedist opined that he believed at least some of the subacromial bursitis, seen on the MRI, was vaccine caused. Exhibit 3 at 17-18. Furthermore, there is a dearth of evidence supporting a different onset or cause.

While these close-in-time histories were based upon information provided by Petitioner, they still should be afforded greater weight than more current representations, as they were uttered contemporaneously with Petitioner's injury for the purposes of obtaining medical care. The Federal Circuit has stated that "[m]edical records, in general, warrant consideration as trustworthy evidence . . . [as they] contain information supplied

[7] At this orthopedic visit, Petitioner identified her pain onset as occurring on September 5, 2019, stating that "pain started *when* she got flu shot." Exhibit 3 at 10 (emphasis added). Although this same medical record contains an entry placing onset the day after vaccination (*id.* at 7), that slightly differing account still supports onset within 48 hours.

to or by health professionals to facilitate diagnosis and treatment of medical conditions." *Cucuras*, 993 F.2d at 1528 (emphasis added). Thus, the Circuit has instructed that information provided by Petitioner to a treater and contained in a contemporaneous record deserves weight, and should not be considered subjective merely because it *came* from a patient, rather than physician.

Although Petitioner delayed seeking treatment for two months and three days, the delay does not provide the strong evidence that Respondent contends. It is often common for a SIRVA petitioner to delay treatment, thinking his/her injury will resolve on its own. Additionally, Petitioner was not seen during this 64-day period for any other illness or medical condition. Such intervening treatment evidence can in many cases either corroborate a petitioner's claim or undermine it – but it is totally absent here. Furthermore, at least one

Accordingly, I find there is preponderant evidence to establish the onset of Petitioner's pain occurred within 48 hours of vaccination.

III. Additional Requirements for Entitlement

A. Legal Standards

In addition to requirements concerning the vaccination received, the pain onset and duration of petitioner's injury (discussed above in Section II), and the lack of other award or settlement,[8] a petitioner must establish that she suffered an injury meeting the Table criteria, in which case causation is presumed, or an injury shown to be caused-in-fact by the vaccination she received. Section 11(c)(1)(C).

The most recent version of the Table, which can be found at 42 C.F.R. § 100.3, identifies the vaccines covered under the Program, the corresponding injuries, and the time period in which the particular injuries must occur after vaccination. Section 14(a). Pursuant to the Vaccine Injury Table, a SIRVA is compensable if it manifests within 48 hours of the administration of a flu vaccine. 42 C.F. R. § 100.3(a)(VIX)(B). The criteria establishing a SIRVA under the accompanying QAI are as follows:

[8] In summary, a petitioner must establish that he received a vaccine covered by the Program, administered either in the United States and its territories or in another geographical area but qualifying for a limited exception; suffered the residual effects of his injury for more than six months, died from his injury, or underwent a surgical intervention during an inpatient hospitalization; and has not filed a civil suit or collected an award or settlement for her injury. *See* Section 11(c)(1)(A)(B)(D)(E).

> Shoulder injury related to vaccine administration (SIRVA). SIRVA manifests as shoulder pain and limited range of motion occurring after the administration of a vaccine intended for intramuscular administration in the upper arm. These symptoms are thought to occur as a result of unintended injection of vaccine antigen or trauma from the needle into and around the underlying bursa of the shoulder resulting in an inflammatory reaction. SIRVA is caused by an injury to the musculoskeletal structures of the shoulder (e.g. tendons, ligaments, bursae, etc.). SIRVA is not a neurological injury and abnormalities on neurological examination or nerve conduction studies (NCS) and/or electromyographic (EMG) studies would not support SIRVA as a diagnosis (even if the condition causing the neurological abnormality is not known). A vaccine recipient shall be considered to have suffered SIRVA if such recipient manifests all of the following:
>
> (i) No history of pain, inflammation or dysfunction of the affected shoulder prior to intramuscular vaccine administration that would explain the alleged signs, symptoms, examination findings, and/or diagnostic studies occurring after vaccine injection;
>
> (ii) Pain occurs within the specified time frame;
>
> (iii) Pain and reduced range of motion are limited to the shoulder in which the intramuscular vaccine was administered; and
>
> (iv) No other condition or abnormality is present that would explain the patient's symptoms (e.g. NCS/EMG or clinical evidence of radiculopathy, brachial neuritis, mononeuropathies, or any other neuropathy).

42 C.F.R. § 100.3(c)(10) (2017).

B. Analysis

As I have determined in this ruling, the record supports a finding that Petitioner suffered pain within 48 hours of vaccination. *See supra* Section II; 42 C.F.R. § 100.3(c)(10)(ii) (second QAI criterion). Respondent has stated no further objections to compensation, and I find Petitioner has otherwise satisfied all criteria for a Table SIRVA injury following receipt of the flu vaccine. There is no evidence of prior left shoulder pain, inflammation, or dysfunction or an alternative cause for Petitioner's symptoms. *See* 42 C.F.R. § 100.3(c)(10)(i), (iv) (first and fourth QAI criteria). And Petitioner exhibited pain and limitations in ROM solely in her left, injured shoulder. *E.g.,* Exhibit 7 at 55 (first PCP

visit on November 8, 2019); Exhibit 3 at 7-8 (first orthopedic visit on January 2, 2020); *see* 42 C.F.R. § 100.3(c)(10)(iii) (third QAI criterion).

Because Petitioner has satisfied the requirements of a Table SIRVA, she need not prove causation. Section 11(c)(1)(C). However, she must satisfy the other requirements of Section 11(c) regarding the vaccination received, the duration and severity of her injury, and the lack of other award or settlement. Section 11(c)(A), (B), and (D). Respondent does not dispute that Petitioner has satisfied these requirements in this case, and the overall record contains preponderant evidence which fulfills these additional requirements.

IV. Appropriate Amount of Compensation

Although I have found Petitioner entitled to compensation, I do not expect the amount awarded for Petitioner's past pain and suffering to be great. As her orthopedist opined, some of the left shoulder conditions seen on the MRI and then repaired during surgery were not necessarily vaccine-related. Exhibit 3 at 17-18; Exhibit 4 at 6. The mere existence of an underlying, but previously asymptomatic, condition or abnormality does not defeat entitlement, but would be relevant when ascertaining the appropriate compensation.

Conclusion

Based on the entire record in this case, I find that Petitioner has provided preponderant evidence satisfying all requirements for a Table SIRVA, and all Vaccine Act requirements for both Table and non-Table claims. Petitioner is entitled to compensation in this case.

IT IS SO ORDERED.

s/Brian H. Corcoran
Brian H. Corcoran
Chief Special Master